

REMARKS

Applicant respectfully requests reconsideration of the restriction requirement. First and foremost, the Examiner's rejection is based on a combination of different categories of claims (i.e. product and process, process and apparatus, apparatus and means, etc.). However, claims 1-20 of the subject application are all of the same category – a process. Therefore, the Examiner's entire rationale in the Office Action is not pertinent to the present claims. Further, as discussed herein, claims 1-20 have unity of invention. See MPEP section 1850(I)-(II) discussing unity of invention, generally, and MPEP 1850(III)(A) discussing the special case of different categories of claims. MPEP section 1850(I)-(II) is controlling here as claims 1-20 are all of the same category. The Applicant respectfully requests withdrawal of the restriction requirement.

“Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression ‘special technical features’ is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.” MPEP 1850(II). Lack of unity of invention “should neither be raised nor maintained on the basis of a narrow, literal or academic approach.” Id. “There should be a broad, practical consideration of the degree of interdependence of the alternatives presented...” Id. In the case of Markush practice, technical interrelationship shall be considered met when the alternatives are of a similar nature. MPEP 1850(III)(B). For example, (A) when all alternatives have a common property or activity, and (B2) all alternatives belong to a recognized class of chemical compounds in the art.” Id. (emphases added). Further, “[n]ucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together.” MPEP 1851(XIII).

First, claims 1-20 are all method claims and of the same category. Second, claims 1-20 share a “special technical feature.” Each of independent claims 1, 5 and 13 involves a step of providing molecular signatures of genes to determine if lung cancer is present. Each claim, or one of the claims dependent from each claim, lists a gene set which, when assayed, may indicate the presence of lung cancer. In the Office Action, the Examiner objects that “each gene is [a] structurally and functionally different product...in order for the claimed species to have unity of

invention, the genes must be structurally and functionally related.” The Applicant respectfully disagrees. The genes do not have to be structurally and functionally related. The genes, however, must share a technical feature that defines a contribution over the prior art. Specifically for Markush groups, the genes must share a common property and belong to a recognized class of chemical compounds. In this case, the common shared property is that each of these genes, when their expression product is analyzed, may indicate the presence of lung cancer. These genes are a recognized class of chemical compounds as genes from H23 cells. This shared relationship among the forty genes listed is sufficient to satisfy the unity of invention requirement.

The Applicant respectfully submits that the Examiner incorrectly relies on MPEP 1850(III) in the Office Action, and that the Examiner’s restriction and election requirement is at odds with MPEP 1850(I)-(II). Withdrawal of the restriction and election requirement is respectfully requested.

ELECTIONS

As required by the MPEP in response to an election and restriction requirement, the Applicant provides the following elections herein:

Election of Invention

The Examiner requires Applicant to elect one of the following six identified inventions: (1) Group I (claims 1-4), (2) Group II (claims 5-12) and (3) Group III (claims 13-20). Applicant elects, without prejudice and with traverse, Group II drawn to a method of identifying a patient suspected of having non-small cell lung cancer. Claims 5-12 encompass the elected invention. Applicant further reserves the right to prosecute the remaining claims in this or a subsequent application.

Election of Species

For Group II, the Examiner requires the Applicant to elect one gene from the genes listed in the claims. The Applicant hereby elects the PCNA gene. Claims 5, 6 and 10-12 are readable on the elected species.

CONCLUSION

Based upon the foregoing remarks, Applicant respectfully requests reconsideration of this restriction requirement and early allowance of the pending claims. Should the Examiner feel that a telephone conference with Applicant's attorney would expedite prosecution of the application; the Examiner is urged to contact the undersigned attorney.

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Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Matthew P. Frederick", written over a horizontal line.

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